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**(54) Stent having a multiplicity of closed circular structures**

Stent mit einer Vielzahl geschlossener kreisförmiger Strukturen

Stent avec une pluralité des structures circulaires fermées

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**EP 0 669 114 B1**

## Description

This invention is in the field of stents for maintaining patency of any one of a multiplicity of vessels of the human body.

In the last decade, many different designs of stents have been used to maintain patency of arteries and other vessels of the human body. In all such devices, hoop strength is an important characteristic. Specifically, the stent must have enough hoop strength to resist the elastic recoil exerted by the vessel into which the stent is placed. The Mass stent described in the U.S. Patent No. 4,553,545 and the Dotter stent described in U.S. Patent No. 4,503,569 are each open helical coils. The Palmaz stent described in the U.S. Patent No. 4,733,665 is of the "chinese finger" design. The Gianturco-Rubin stent currently sold by Cook, Inc. is another stent design which like the stents of Mass, Dotter and Palmaz does not have any closed circular member to optimize hoop strength.

European patent application 0,566,807 describes a post-deployment stent formed by joining together a number of unitary elements. Once constructed, the stent has a number of closed rings connected by straight longitudinals.

The ideal arterial stent utilizes a minimum wire size of the stent elements to minimize thrombosis at the stent site after implantation. The ideal arterial stent also possesses sufficient hoop strength to resist elastic recoil of the artery. The optimum design for maximizing hoop strength is a closed circular structure which has a small diameter when percutaneously inserted into a vessel and which expands into the form of multiplicity of closed circular structures (i.e. rings) when expanded outward against the vessel wall.

In accordance with a first aspect of the invention, there is provided a post-deployment stent structure for maintaining patency of a vessel of a human body, the stent structure having a multiplicity of closed, generally circular rings, the plane of each ring being generally parallel to the plane of each adjacent ring, the rings having a generally common longitudinal axis which is perpendicular to the plane of each ring with the rings being spaced apart from each other and having a multiplicity of structures forming longitudinals, the longitudinals being fixedly attached to the rings, the stent structure being characterised by:

at least two longitudinals having an undulating shape so as to enhance longitudinal flexibility.

In accordance with another aspect of the invention there is provided an initial structure that is capable of being formed into a pre-deployment stent structure which in turn is capable of being deployed into a post-deployment stent structure according to the first aspect of the invention for placement within a vessel of the human body, the initial structure being characterised by:

a multiplicity of flat ovals which in the post-deployment stent form said multiplicity of closed, generally circular rings, the plane of each oval being generally parallel to the plane of all other ovals, the ovals having a common longitudinal axis which is perpendicular to the plane of each oval and which longitudinal axis passes through the geometric centre of the ovals; and

a multiplicity of longitudinals fixedly attached to the ovals, at least two of the longitudinals having an undulating shape so as to enhance longitudinal flexibility, the longitudinals being positioned onto the ovals so as to be generally parallel to the longitudinal axis of the ovals, at least one of the longitudinals being spaced apart from all other longitudinals.

In accordance with a further aspect of the invention there is provided a pre-deployment stent structure which is capable of being deployed into a post-deployment stent structure according to the first aspect of the invention for placement within a vessel of the human body, the pre-deployment structure being formed from an initial structure being characterised in that the initial structure consists of a multiplicity of flat ovals which in the post-deployment stent form said multiplicity of closed, generally circular rings, the plane of each oval of said initial structure being generally parallel to the plane of all other ovals, the ovals also having a minor axis and a major axis dimension and a major axis dimension, the ovals having a common longitudinal axis which is perpendicular to the plane of each oval and which longitudinal axis passes through the geometric centre of the ovals, and a multiplicity of longitudinals fixedly attached to the ovals, the longitudinals being positioned onto the ovals from a single metallic structure, at least two of the longitudinals having an undulating shape so as to enhance longitudinal flexibility, and the pre-deployment stent structure being formed by folding the ovals about each oval's minor axis in nested relation each with respect to the other, the pre-deployment stent structure being adapted to form a post-deployment stent structure having a multiplicity of generally circular rings that are formed from the ovals.

An embodiment of the invention provides an expandable stent that can be used in an artery or any other vessel of the human body which, when expanded, forms a multiplicity of generally circular rings whose closed structure optimizes hoop strength so as to minimize elastic recoil of the vessel into which the stent is inserted. Furthermore, the structure of an embodiment of the stent according to the present invention is initially in the form of folded ellipses or ovals which can be formed to a small diameter for percutaneous insertion by means of a stent delivery catheter. The ovals can be joined to each other by at least two undulating shaped wires which are called "longitudinals" which serve to space the deployed rings within the vessel. Undulating

longitudinals can be employed in either straight or highly curved vessels such as some coronary arteries.

An embodiment of the invention provides a stent having a maximum hoop strength by the employment of closed, generally circular structures which are in fact rings.

In an embodiment of the invention the rings are initially in the form of ovals that can be folded to fit onto a cylindrical structure at a distal portion of a stent delivery catheter.

In an embodiment of the invention the fully deployed rings are spaced apart by means of longitudinals which comprise at least two undulating wires that are placed to be generally parallel to the longitudinal axis of the vessel into which the stent is deployed.

In an embodiment of the invention the pre-deployment stent structure is formed as a single piece out of metal tube having a smaller inside diameter as compared to the outside diameter of an expandable balloon onto which the pre-deployment stent is mounted.

An embodiment of the invention is described hereinafter, by way of example only with reference to the accompanying drawings, in which:

Fig. 1 is a side view of a stent after it has been deployed; i.e., in its post-deployment form;

Fig. 2 is a transverse cross section at section 2-2 of Fig. 1 illustrating how the longitudinals are joined to the rings;

Fig. 3 is a cross section at section 3-3 of Fig. 2 showing the joining of a single ring to the longitudinals;

Fig. 4 is a side view of a stent prior to being mounted onto a stent delivery catheter; i.e., in the form of an initial structure;

Fig. 5 is a transverse cross section at section 5-5 of Fig. 4 illustrating how the longitudinals are joined to the ovals;

Fig. 6 is a side view of a pre-deployment form of the stent structure in which the ovals have been folded into a small diameter cylinder that is placed around a deflated balloon situated near the distal end of a stent delivery catheter;

Fig. 7 is a partial side view of a pre-deployment stent structure showing only two of a multiplicity of folded ovals formed around an expandable balloon in which the ovals are folded in an alternative manner as compared with Fig. 6;

Fig. 8 is a side view of a post-deployment stent structure in accordance with the invention which utilizes two undulating longitudinals on opposite sides

of the stent for improved placement in curved vessels; and

Fig. 9 is a side view of a stent as etched out of a small diameter metal cylinder as a single piece of metal.

Fig. 1 is a side view of an embodiment of a cylindrical stent 1 shown in its post-deployment configuration. The stent 1 has a multiplicity of rings 2 which are spaced apart by four wires called longitudinals. As seen in Figs. 1 and 2, at the top of the stent is longitudinal 4T, at the bottom is longitudinal 4B, at the left side is longitudinal 4L and at the right side is longitudinal 4R. Although FIGS. 1 and 2 show 7 rings and 4 longitudinals, it is apparent that the stent can be made longer by adding rings or increasing the separation between rings. In a similar manner, the stent can be made shorter by reducing the number of rings or decreasing the spacing between rings. Also variable spacing of the rings is envisioned for accomplishing a variety of purposes including increased hoop strength at a particular section of the stent. Also, it is envisioned that the two or more longitudinals could be utilized for this stent design with a maximum number being 32.

FIGS. 2 and 3 illustrate the joining of the longitudinals to the rings. Specifically the longitudinals can be placed into cutouts in the form of notches 5 located on the outside perimeter of the ring 2. The longitudinals can then be spot welded, adhesively bonded or joined by any variety of means to the rings 2. It is also envisioned that the longitudinals could be placed on the inside perimeter of the ring 2, or holes could be mechanically or laser drilled through the ring 2 for placement therethrough of the longitudinals.

FIGS. 4 and 5 illustrate a stent 1' shown in one particular form in which it could be fabricated; i.e., in an initial structure form. Specifically, FIGS. 4 and 5 show that this initial form of the stent 1' is a multiplicity of parallel ellipses or ovals 2' each oval having the same minor axis dimension m and major axis dimension M. The oval's minor axis passes through the center of the longitudinals 4L and 4R. The oval's major axis passes through the center of the longitudinals 4T and 4B. It is important to note that, if it is desired to have a final outside diameter D (as seen in FIG. 2) of the ring 2 after it is fully deployed, then it can be shown that D is given by the equation  $D^2 = 1/2 (m^2 + M^2)$ .

To place the stent design of FIGS. 4 and 5 onto a balloon that is mounted near the distal end of a stent delivery catheter, it is necessary to fold the ovals 2' around that balloon. Specifically, the pre-deployment cylindrical stent 1" can be formed onto an expandable balloon 6 as shown in FIG. 6 by folding the ovals 2' about the dotted line F (which is the minor axis of the oval 2') as shown in FIG. 5. Specifically, as seen in FIG. 4, the top and bottom of the ovals 2' could be held stationary while the side longitudinals 4R and 4L are

pushed to the left which results in the pre-deployment structure which is shown as the stent 1" in FIG. 6. An optimum design has the folded ovals 2" as shown in FIG. 6 with the stent 1" being a cylinder whose outside diameter is equal in size to the minor axis dimension m. When the balloon 6 of FIG. 6 is expanded, the pre-deployment stent 1" structure forms the post-deployment stent 1 structure having circular rings 2 as shown in FIGS. 1 and 2.

The stent 1'" is an alternative embodiment for a pre-deployment structure of the stent as it is placed onto a balloon. Specifically, FIG. 7 shows 2 folded rings 2'" of a multiple ring stent 1'" . The stent 1'" being formed by holding the top and bottom of the stent 1' of FIG. 4 stationary while pushing the longitudinal 4R to the left and pushing the longitudinal 4L to the right. Like the stent 1" of FIG. 6, when mounted onto a balloon, the stent 1'" has a cylindrical shape with a diameter equal to the dimension m.

Figs. 1 to 7 inclusive illustrate stents that employ longitudinals that are formed from generally straight wires. Fig. 8 shows an embodiment of a stent 10 according to the present invention that has two undulating longitudinals. Specifically, the left side longitudinal 14L (shown as dotted lines) and the right side longitudinal 14R are each undulating shaped longitudinals. A stent such as stent 10 could have two or more undulating longitudinals. Such a stent would bend more easily during insertion into a vessel and would be more readily adaptable for placement in curved vessels such as some coronary arteries.

Typically, the rings and longitudinals of the stents would be made of the same material. Typical metals used for such a stent would be stainless steel, tantalum, titanium, or a shape memory metal such as Nitinol. If Nitinol is used, the stent would be heat treated into the shape at body temperature having circular rings 2 as shown in FIGS. 1 and 2. The rings could then be distorted into ovals as shown in FIGS. 4 and 5 and then mounted onto a stent delivery catheter which does not employ a balloon but is of the more general shape described in the previously cited U.S. Patent No. 4,553,545 by C.T. Dotter. Such a design would provide the desired stent structure having a multiplicity of generally circular rings instead of the Dotter design of a helical spring which inherently has a lesser hoop strength as compared to the present invention.

It should be understood that once the ovals are folded onto a stent delivery catheter, when they fully deploy, they do not form perfectly circular rings as shown in FIG. 2, but rather they are of a generally circular shape. Such comparatively small deviations from an exactly circular shape do not appreciably decrease hoop strength because they are in fact closed structures that are almost exactly circular.

It should also be understood that at least part of the end rings of the stent could be fabricated from or coated with a radiopaque metal such as tantalum or gold to pro-

vide a fluoroscopic indication of the stent position within a vessel. However, the other rings and the longitudinals could be made from a much less dense metal which would provide less obscuration of the central region within the stent. For example, the stent rings and longitudinals could all be fabricated from titanium or a titanium alloy except the end rings which could be formed from gold which is then plated with titanium. Thus, the entire outside surface of the stent would be titanium, which is known to be a comparatively non-thrombogenic metal while the gold in the end rings provides an improved fluoroscopic image of the stent extremities.

The dimensions of stent rings are typically 0.1 to 0.3 mm thick, with a width of 0.1 to 0.5 mm and an outside diameter D between 2.0 and 30.0 mm depending on the luminal diameter of the vessel into which it is inserted. The length of the stent could be between 1 and 10 cm. The wire diameter for the longitudinals would typically be between 0.05 and 0.5 mm.

Although the designs of FIGS. 1 through 7 inclusive illustrate separate longitudinals attached to a multiplicity of rings, this invention also contemplates an initial stent structure which is chemically etched from thin-walled tubing having an oval transverse cross section. Thus the oval and longitudinals would be formed from a single piece of metal thus precluding the need for attaching the longitudinals to the rings. In a similar manner laser or EDM machining could be used to form the stent from a thin-walled tube.

It is further anticipated that a pre-deployment stent structure 20 as shown in Fig. 9 could be formed from a thin-walled cylindrical tube whose inside diameter is slightly smaller than the outside diameter of the balloon 6 shown in Fig. 6. A pattern such as that shown in either Fig. 6 or Fig. 7 could be photoetched onto a thin-walled metal cylinder. The one piece structure 20 shown in Fig. 9 has folded ovals 22 and longitudinals 23T, 24B, 24R and (not shown) 24L. This pre-deployment stent structure 20 could then be mounted onto the expandable balloon; the stent having sufficient elastic recoil to firmly grasp down onto the balloon.

Various other modifications, adaptations, and alternative designs are of course possible in light of the above teachings and within the scope of the invention.

## Claims

1. A post-deployment stent structure (10) for maintaining patency of a vessel of a human body, the stent structure (10) having a multiplicity of closed, generally circular rings (12), the plane of each ring being generally parallel to the plane of each adjacent ring (12), the rings (12) having a generally common longitudinal axis which is perpendicular to the plane of each ring (12) with the rings (12) being spaced apart from each other and having a multiplicity of structures forming longitudinals (14), the longitudinals (14) being fixedly attached to the rings (12),

the stent structure (10) being characterised by:

at least two longitudinals (14L, 14R) having an undulating shape so as to enhance longitudinal flexibility.

2. The stent of Claim 1, wherein the longitudinals (14) comprise a pair of top and bottom longitudinals and a pair of side longitudinals, the top and bottom longitudinals being adapted to maintain an essentially unchanged shape in the absence of the multiplicity of generally circular rings, and the side longitudinals having said undulating shape.
3. The stent of Claim 1 or Claim 2, wherein the longitudinals (14) are of unitary construction with the generally circular rings (12) from a single piece of thin-walled metal tubing.
4. The stent of Claim 1 or Claim 2, wherein the rings (12) have a multiplicity of cutouts (5) for the placement therethrough of the longitudinals (14), the longitudinals being generally elongated structures that lie parallel to the common longitudinal axis of the generally circular rings (12).
5. The stent of claim 4, wherein the cutouts (5) on the rings are formed in unitary construction with the longitudinals (14) from a single piece of metal.
6. The stent of claim 5, wherein the single piece of metal is generally in the form of a thin-walled cylinder.
7. The stent of claim 1, wherein at least one of the longitudinals (14) is spaced apart from all other longitudinals (14).
8. The stent of claim 1, wherein each longitudinal (14) is spaced apart from every other longitudinal (14).
9. The stent of claim 1, wherein at least one of the longitudinals (14) is a linearly directed, elongated structure.
10. The stent of claim 1, wherein the rings (12) and longitudinals (14) are made from titanium.
11. The stent of claim 1, wherein the multiplicity of circular rings (12) has exactly two end rings which are those rings which have an adjacent ring on only one side and at least one interior ring which has adjacent rings on both sides, at least some portion of the end rings being formed from a metal having a higher density as compared to the density of the metal of the at least one interior ring.
12. The stent of claim 1, wherein the stent is formed

from a metal having a shape memory characteristic.

13. An initial structure (1') that is capable of being formed into a pre-deployment stent structure which in turn is capable of being deployed into a post-deployment stent structure as claimed in any preceding claim for placement within a vessel of the human body, the initial structure being characterised by:

a multiplicity of flat ovals (2') which in the post-deployment stent form said multiplicity of closed, generally circular rings (12), the plane of each oval being generally parallel to the plane of all other ovals, the ovals having a common longitudinal axis which is perpendicular to the plane of each oval and which longitudinal axis passes through the geometric centre of the ovals; and

a multiplicity of longitudinals (14) fixedly attached to the ovals (2'), at least two of the longitudinals having an undulating shape so as to enhance longitudinal flexibility, the longitudinals being positioned onto the ovals so as to be generally parallel to the longitudinal axis of the ovals, at least one of the longitudinals being spaced apart from all other longitudinals.

14. The initial structure of claim 13 wherein the ovals (2') and the longitudinals (14) are unitary.
15. A pre-deployment stent structure (20) which is capable of being deployed into a post-deployment stent structure as claimed in any of claims 1 to 12 for placement within a vessel of the human body, the pre-deployment structure being formed from an initial structure being characterised in that the initial structure consists of a multiplicity of flat ovals which in the post-deployment stent form said multiplicity of closed, generally circular rings (12), the plane of each oval of said initial structure being generally parallel to the plane of all other ovals, the ovals also having a minor axis and a major axis and a minor axis dimension and a major axis dimension, the ovals having a common longitudinal axis which is perpendicular to the plane of each oval and which longitudinal axis passes through the geometric centre of the ovals, and a multiplicity of longitudinals fixedly attached to the ovals, the longitudinals being positioned onto the ovals from a single metallic structure, at least two of the longitudinals having an undulating shape so as to enhance longitudinal flexibility, and the pre-deployment stent structure being formed by folding the ovals about each oval's minor axis in nested relation each with respect to the other, the pre-deployment stent structure being adapted to form a post-deployment stent structure

- having a multiplicity of generally circular rings that are formed from the ovals.
16. The pre-deployment stent structure of claim 15 wherein the ovals (2') are folded around an expandable balloon (6) located near the distal end of a stent delivery catheter. 5
17. The pre-deployment stent structure of claim 15 wherein the ovals (2') are folded around the oval's minor axis to form a pre-deployment structure of a generally cylindrical shape that can be mounted onto a stent delivery catheter. 10
18. The pre-deployment stent structure of claim 15 wherein one side of the ovals (2') is folded in one direction and the opposite side of the ovals is folded in the opposite direction to form a pre-deployment structure of a generally cylindrical shape. 15
19. The pre-deployment stent structure of claim 15, wherein the outer diameter of the generally cylindrical pre-deployment stent structure is approximately the same as the minor axis dimension of the oval (2'). 20
20. The pre-deployment stent structure of claim 17, wherein the stent structure formed from the single metallic structure is a cylinder that is smaller in its inside diameter as compared to the outside diameter of an expandable balloon (6) located at a distal portion of a stent delivery catheter onto which the stent structure is mounted. 30
21. The pre-deployment stent structure of any of claims 15 to 20, wherein said at least two longitudinals having an undulating shape (14L, 14R) comprise a multiplicity of straight sections and undulating sections with each straight section being joined continuously to an undulating section, the straight sections of all of the longitudinal structures being generally parallel to the longitudinal axis of the stent, the undulating sections of each longitudinal structure being of a generally curved shape so as to allow each undulating longitudinal structure to readily expand and contract in length during insertion of the stent in to a curved vessel. 35
22. The pre-deployment stent structure of claim 21, wherein each undulating section is in the general form of a sine wave. 40
- 45

#### Patentansprüche

1. Nachentfaltungsstent (10) zur Aufrechterhaltung der Durchgängigkeit eines Gefäßes eines menschlichen Körpers, wobei der Stent (10) mehrere geschlossene, allgemein runde Ringe (12) hat, die

Ebene jedes Ringes allgemein parallel zu der Ebene des jeden benachbarten Ringes (12) ist, die Ringe (12) eine allgemein gemeinsame Längsachse haben, welche senkrecht zu der Ebene eines jeden Ringes (12) ist, die Ringe (12) einen Abstand voneinander haben und mehrere Strukturen haben, die Längselemente (14) bilden, und die Längselemente (14) an den Ringen (12) fest befestigt sind, wobei der Stent (10) durch wenigstens zwei Längselemente (14L, 14R) gekennzeichnet ist, die eine Wellenform besitzen, um so die Längsflexibilität zu verbessern.

2. Stent nach Anspruch 1, bei dem die Längselemente (14) ein Paar von oberen und unteren Längselementen und ein Paar von Seitenlängselementen umfassen, wobei die oberen und unteren Längselemente so ausgebildet sind, daß sie in Abwesenheit der mehreren allgemein runden Ringe eine im wesentlichen unveränderte Form behalten, und die Seitenlängselemente die Wellenform haben.
3. Stent nach Anspruch 1 oder Anspruch 2, bei dem die Längselemente (14) einheitlichen Bau mit den allgemein runden Ringen (12) aus einem einzigen Stück eines dünnwandigen Metallschlauches haben.
4. Stent nach Anspruch 1 oder Anspruch 2, bei dem die Ringe (12) mehrere Ausschnitte (5) zum Platzieren der Längselemente (14) durch sie hindurch haben, wobei die Längselemente allgemein längliche Bauteile sind, die parallel zu der gemeinsamen Längsachse der allgemein runden Ringe (12) liegen.
5. Stent nach Anspruch 4, bei dem die Ausschnitte (5) an den Ringen in einheitlicher Bauweise mit den Längselementen (14) aus einem einzigen Metallstück geformt sind.
6. Stent nach Anspruch 5, bei dem das einzelne Metallstück allgemein in der Form eines dünnwandigen Zylinders vorliegt.
7. Stent nach Anspruch 1, bei dem wenigstens eines der Längselemente (14) von allen anderen Längselementen (14) einen Abstand hat.
8. Stent nach Anspruch 1, bei dem jedes Längselement (14) von jedem anderen Längselement (14) einen Abstand hat.
9. Stent nach Anspruch 1, bei dem wenigstens eines der Längselemente (14) linear ausgerichtete, längliche Struktur hat.

10. Stent nach Anspruch 1, bei dem die Ringe (12) und die Längselemente (14) aus Titan bestehen.
11. Stent nach Anspruch 1, bei dem die mehreren runden Ringe (12) genau zwei Endringe haben, die jene Ringe sind, die nur auf einer Seite einen benachbarten Ring haben, und wenigstens einen Innenring haben, der auf beiden Seiten benachbarte Ringe hat, wobei wenigstens ein Teil der Endringe aus einem Metall mit einer höheren Dichte gegenüber der Dichte des Metalles des wenigstens einen Innenringes gebildet ist.
12. Stent nach Anspruch 1, bei dem der Stent aus einem Metall mit der Eigenschaft eines Formierungsvermögens gebildet ist.
13. Ausgangsstruktur (1'), die zu einem Vorentfaltungsstent gebildet werden kann, welcher seinerseits zu einem Nachentfaltungsstent nach einem der vorangehenden Ansprüche zur Platzierung in einem Gefäß des menschlichen Körpers entfaltet werden kann, gekennzeichnet durch:
- mehrere flache Ovale (2'), die in dem Nachentfaltungsstent die mehreren geschlossenen, allgemeinen runden Ringe (12) bilden, wobei die Ebene eines jeden Ovals allgemein parallel zu der Ebene aller anderen Ovale ist und die Ovale eine gemeinsame Längsachse haben, die senkrecht zu der Ebene jedes Ovals liegt und durch den geometrischen Mittelpunkt der Ovale verläuft, und
- mehrere Längselemente (14), die fest an den Ovalen (2') befestigt sind, wobei wenigstens zwei der Längselemente eine Wellenform haben, um so die Längsflexibilität zu verbessern, und die Längselemente auf den Ovalen so positioniert sind, daß sie allgemein parallel zu der Längsachse der Ovale sind, wobei wenigstens eines der Längselemente einen Abstand von allen anderen Längselementen besitzt.
14. Ausgangsstruktur nach Anspruch 13, bei der Ovale (2') und die Längselemente (14) einheitlich sind.
15. Vorentfaltungsstent (20), der zu einem Nachentfaltungsstent nach einem der Ansprüche 1 bis 12 zur Platzierung in einem Gefäß des menschlichen Körpers entfaltet werden kann, wobei die Vorentfaltungsstruktur aus einer Ausgangsstruktur gebildet ist, die dadurch gekennzeichnet ist, daß die Ausgangsstruktur aus mehreren flachen Ovalen, die in dem Nachentfaltungsstent die mehreren geschlossenen, allgemein runden Ringe (12) bilden, wobei die Ebene eines jeden Ovals der Ausgangsstruktur
- allgemein parallel zu der Ebene aller anderen Ovale liegt, die Ovale auch eine kleinere Achse und eine größere Achse und eine kleinere Achsenabmessung und eine größere Achsenabmessung haben und die Ovale eine gemeinsame Längsachse besitzen, die senkrecht zu der Ebene eines jeden Ovals ist und durch den geometrischen Mittelpunkt der Ovale verläuft, und aus mehreren fest an den Ovalen befestigten Längselementen besteht, wobei die auf den Ovalen positionierten Längselemente ein einzelnes Metallbauteil bilden, wenigstens zwei der Längselemente eine Wellenform haben, um so die Längsflexibilität zu verbessern, und der Vorentfaltungsstent durch Falten der Ovale um jede kleinere Achse des Ovals jeweils in geschachtelter Beziehung zu dem anderen gebildet ist, wobei der Vorentfaltungsstent so ausgebildet ist, daß er einen Nachentfaltungsstent mit mehreren allgemein runden Ringen bildet, die aus den Ovalen gebildet werden.
16. Vorentfaltungsstent nach Anspruch 15, bei dem die Ovale (2') um einen ausdehnbaren Ballon (6) gefaltet sind, der nahe dem distalen Ende des Stentabgabekatheters angeordnet ist.
17. Vorentfaltungsstent nach Anspruch 15, bei dem die Ovale (2') um die kleinere Achse des Ovals unter Bildung einer Vorentfaltungsstruktur von allgemein zylindrischer Form, die auf einem Stentabgabekatheter befestigt werden kann, gefaltet sind.
18. Vorentfaltungsstent nach Anspruch 15, bei dem eine Seite der Ovale (2') in einer Richtung und die gegenüberliegende Seite der Ovale in der entgegengesetzten Richtung gefaltet ist, um eine Vorentfaltungsstruktur von allgemein zylindrischer Form zu bilden.
19. Vorentfaltungsstent nach Anspruch 15, bei dem der Außendurchmesser der allgemein zylindrischen Vorentfaltungsstentstruktur etwa der gleiche wie die Abmessung der kleineren Achse des Ovals (2') ist.
20. Vorentfaltungsstent nach Anspruch 17, bei dem die aus der einzelnen Metallstruktur gebildete Stentstruktur ein Zylinder ist, der kleiner in seinem Innendurchmesser als der Außendurchmesser eines ausdehnbaren Ballons (16) ist, welcher an einem distalen Abschnitt eines Stentabgabekatheters, auf welchem der Stent befestigt ist, angeordnet ist.
21. Vorentfaltungsstent nach einem der Ansprüche 15 bis 20, bei dem die wenigstens zwei Längselemente mit Wellenform (14L, 14R) mehrere gerade Abschnitte und wellenförmige Abschnitte umfassen, wobei jeder gerade Abschnitt kontinuierlich mit

einem wellenförmigen Abschnitt verbunden ist, die geraden Abschnitte aller Längselementstrukturen allgemein parallel zu der Längsachse des Stents sind und die wellenförmigen Abschnitte jeder Längselementstruktur eine allgemein gekrümmte Form haben und es so erlauben, daß jede wellenförmige Längselementstruktur während des Einsetzens des Stents in ein gekrümmtes Gefäß sich leicht ausdehnt und zusammenzieht.

22. Vorentfaltungsstent nach Anspruch 21, bei dem jeder wellenförmige Abschnitt die allgemeine Form einer Sinuswelle hat.

#### Revendications

1. Structure de stent à post-déploiement (10) pour maintenir l'état non obstrué d'un vaisseau d'un corps humain, la structure de stent (10) comportant une multiplicité d'anneaux fermés globalement circulaires (12), le plan de chaque anneau étant globalement parallèle au plan de chaque anneau (12) adjacent, les anneaux (12) ayant un axe longitudinal globalement commun qui est perpendiculaire au plan de chaque anneau (12) avec les anneaux (12) écartés les uns des autres et ayant une multiplicité de structures formant des éléments longitudinaux (14), les éléments longitudinaux (14) étant fixés aux anneaux (12), la structure de stent (10) étant caractérisée par :

au moins deux éléments longitudinaux (14L, 14R) qui ont une forme ondulée de façon à améliorer la flexibilité longitudinale.

2. Stent selon la revendication 1, dans lequel les éléments longitudinaux (14) comprennent deux éléments longitudinaux supérieur et inférieur et deux éléments longitudinaux latéraux, les éléments longitudinaux supérieur et inférieur étant conçus pour conserver une forme essentiellement inchangée en l'absence de la multiplicité des anneaux globalement circulaires, et les éléments longitudinaux latéraux ayant ladite forme ondulée.

3. Stent selon la revendication 1 ou la revendication 2, dans lequel les éléments longitudinaux (14) forment une construction monobloc avec les anneaux globalement circulaires (12) à partir d'une seule pièce de tuyau métallique à paroi mince.

4. Stent selon la revendication 1 ou la revendication 2, dans lequel les anneaux (12) ont une multiplicité de découpes (5) destinées au positionnement à travers elles des éléments longitudinaux (14), les éléments longitudinaux étant des structures globalement allongées qui s'étendent parallèlement à l'axe longitudinal commun des anneaux glo-

balement circulaires (12).

5. Stent selon la revendication 4, dans lequel les découpes (5) sur les anneaux sont formées selon une construction monobloc avec les éléments longitudinaux (14) à partir d'une seule pièce de métal.

6. Stent selon la revendication 5, dans lequel la seule pièce de métal se présente globalement sous la forme d'un cylindre à paroi mince.

7. Stent selon la revendication 1, dans lequel au moins un des éléments longitudinaux (14) est écarté de tous les autres éléments longitudinaux (14).

8. Stent selon la revendication 1, dans lequel chaque élément longitudinal (14) est écarté de chaque autre élément longitudinal (14).

9. Stent selon la revendication 1, dans lequel au moins un des éléments longitudinaux (14) est une structure allongée dirigée linéairement.

10. Stent selon la revendication 1, dans lequel les anneaux (12) et les éléments longitudinaux (14) sont réalisés à partir de titane.

11. Stent selon la revendication 1, dans lequel la multiplicité d'anneaux circulaires (12) comporte exactement deux anneaux d'extrémité qui sont ces anneaux ayant un anneau adjacent seulement d'un côté et au moins un anneau intérieur qui a des anneaux adjacents des deux côtés, au moins une certaine partie des anneaux d'extrémité étant formée à partir d'un métal ayant une densité plus élevée comparé à la densité du métal de l'au moins un anneau intérieur.

12. Stent selon la revendication 1, dans lequel le stent est formé à partir d'un métal ayant une caractéristique de mémoire de forme.

13. Structure initiale (1') qui est capable d'adopter la forme d'une structure de stent à pré-déploiement qui, à son tour, est capable d'être déployée en une structure de stent à post-déploiement selon l'une quelconque des revendications précédentes pour être placée à l'intérieur d'un vaisseau du corps humain, la structure initiale étant caractérisée par :

une multiplicité d'ovales plans (2') qui, dans le stent à post-déploiement, forment ladite multiplicité d'anneaux fermés globalement circulaires (12), le plan de chaque ovale étant globalement parallèle au plan de tous les autres ovales, les ovales ayant un axe longitudinal commun qui est perpendiculaire au plan



- de chaque ovale et l'axe longitudinal traversant le centre géométrique des ovales ; et une multiplicité d'éléments longitudinaux (14) fixés aux ovales (2'), au moins deux des éléments longitudinaux ayant une forme ondulée de façon à améliorer la flexibilité longitudinale, les éléments longitudinaux étant positionnés sur les ovales de façon à être globalement parallèles à l'axe longitudinal des ovales, au moins l'un des éléments longitudinaux étant écarté de tous les autres éléments longitudinaux.
14. Structure initiale selon la revendication 13, dans laquelle les ovales (2') et les éléments longitudinaux (14) sont monoblocs.
15. Structure de stent à pré-déploiement (20) qui est capable d'être déployée en une structure de stent à post-déploiement selon l'une quelconque des revendications 1 à 12, pour être placée à l'intérieur d'un vaisseau du corps humain, la structure à pré-déploiement, étant formée à partir d'une structure initiale, caractérisée en ce que la structure initiale consiste en une multiplicité d'ovales plans qui, dans le stent à post-déploiement, forment ladite multiplicité d'anneaux fermés globalement circulaires (12), le plan de chaque ovale de ladite structure initiale étant globalement parallèle au plan de tous les autres ovales, les ovales ayant aussi un petit axe et un grand axe ainsi qu'une dimension de petit axe et une dimension de grand axe, les ovales ayant un axe longitudinal commun qui est perpendiculaire au plan de chaque ovale et lequel axe longitudinal traverse le centre géométrique des ovales, et une multiplicité d'éléments longitudinaux fixés aux ovales, les éléments longitudinaux étant positionnés sur les ovales à partir d'une seule structure métallique, au moins deux des éléments longitudinaux ayant une forme ondulée de façon à améliorer la flexibilité longitudinale, et la structure de stent à pré-déploiement étant formée en pliant les ovales autour de chaque petit axe d'ovale selon une relation d'emboîtement des uns par rapport aux autres, la structure de stent à pré-déploiement étant conçue pour former une structure de stent à post-déploiement munie d'une multiplicité d'anneaux globalement circulaires qui sont formés à partir des ovales.
16. Structure de stent à pré-déploiement selon la revendication 15, dans laquelle les ovales (2') sont pliés autour d'un ballon extensible (6) situé près de l'extrémité distale d'un cathéter de livraison de stent.
17. Structure de stent à pré-déploiement selon la revendication 15, dans laquelle les ovales (2') sont pliés autour des petits axes d'ovale de façon à former une structure à pré-déploiement de forme globalement cylindrique qui peut être montée sur un cathéter de livraison de stent.
18. Structure de stent à pré-déploiement selon la revendication 15, dans laquelle un côté des ovales (2') est plié dans une direction et le côté opposé des ovales est plié dans la direction opposée de façon à former une structure à pré-déploiement de forme globalement cylindrique.
19. Structure de stent à pré-déploiement selon la revendication 15, dans laquelle le diamètre extérieur de la structure de stent à pré-déploiement globalement cylindrique est approximativement le même que la dimension du petit axe de l'ovale (2').
20. Structure de stent à pré-déploiement selon la revendication 17, dans laquelle la structure de stent formée à partir de la seule structure métallique est un cylindre qui a un diamètre intérieur plus petit comparé au diamètre extérieur d'un ballon extensible (6) situé au niveau d'une partie distante d'un cathéter de livraison de stent sur lequel la structure de stent est montée.
21. Structure de stent à pré-déploiement selon l'une quelconque des revendications 15 à 20, dans laquelle lesdits au moins deux éléments longitudinaux (14L, 14R) ayant une forme ondulée comprennent une multiplicité de sections droites et de sections ondulées dont chaque section droite est jointe de façon continue à une section ondulée, les sections droites de toutes les structures longitudinales étant globalement parallèles à l'axe longitudinal du stent, les sections ondulées de chaque structure longitudinale ayant une forme globalement recourbée de façon à permettre à chaque structure longitudinale ondulée de s'allonger et de se rétrécir aisément pendant l'insertion du stent à l'intérieur d'un vaisseau recourbé.
22. Structure de stent à pré-déploiement selon la revendication 21, dans laquelle chaque section ondulée a globalement la forme d'une courbe en sinus.

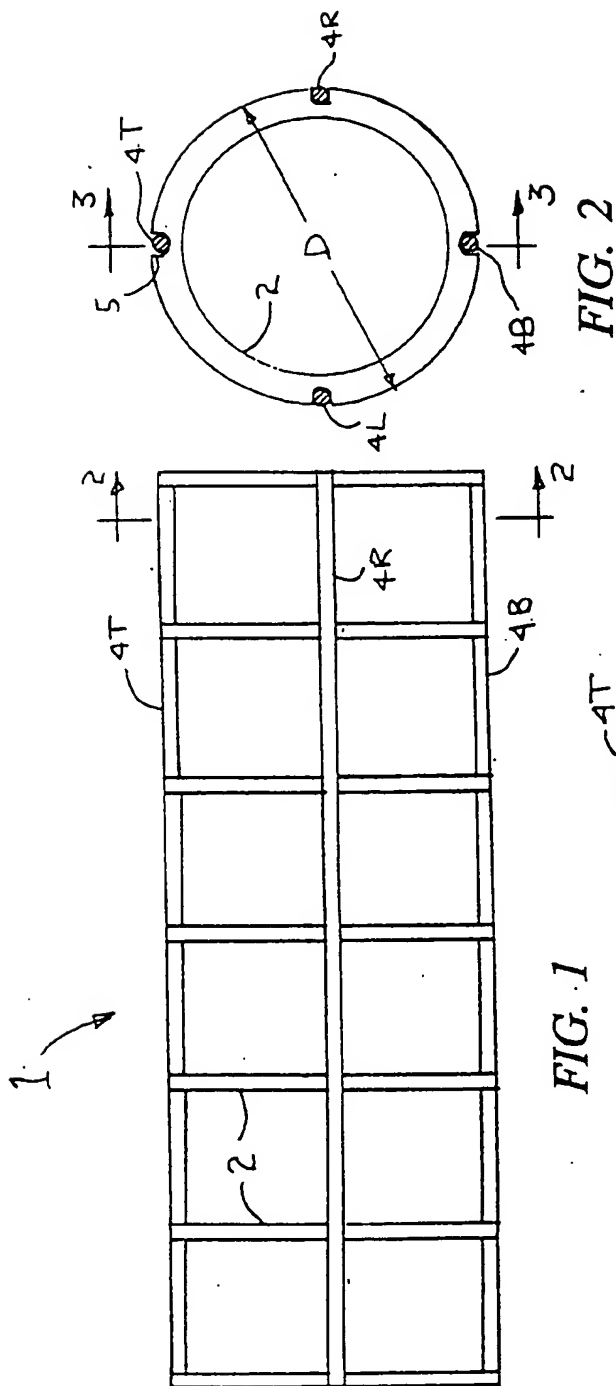


FIG. 1

FIG. 2

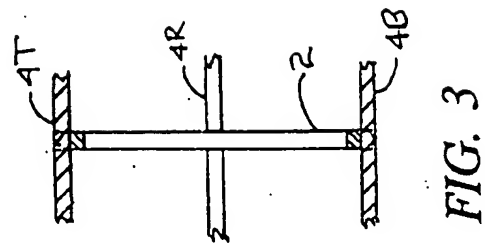
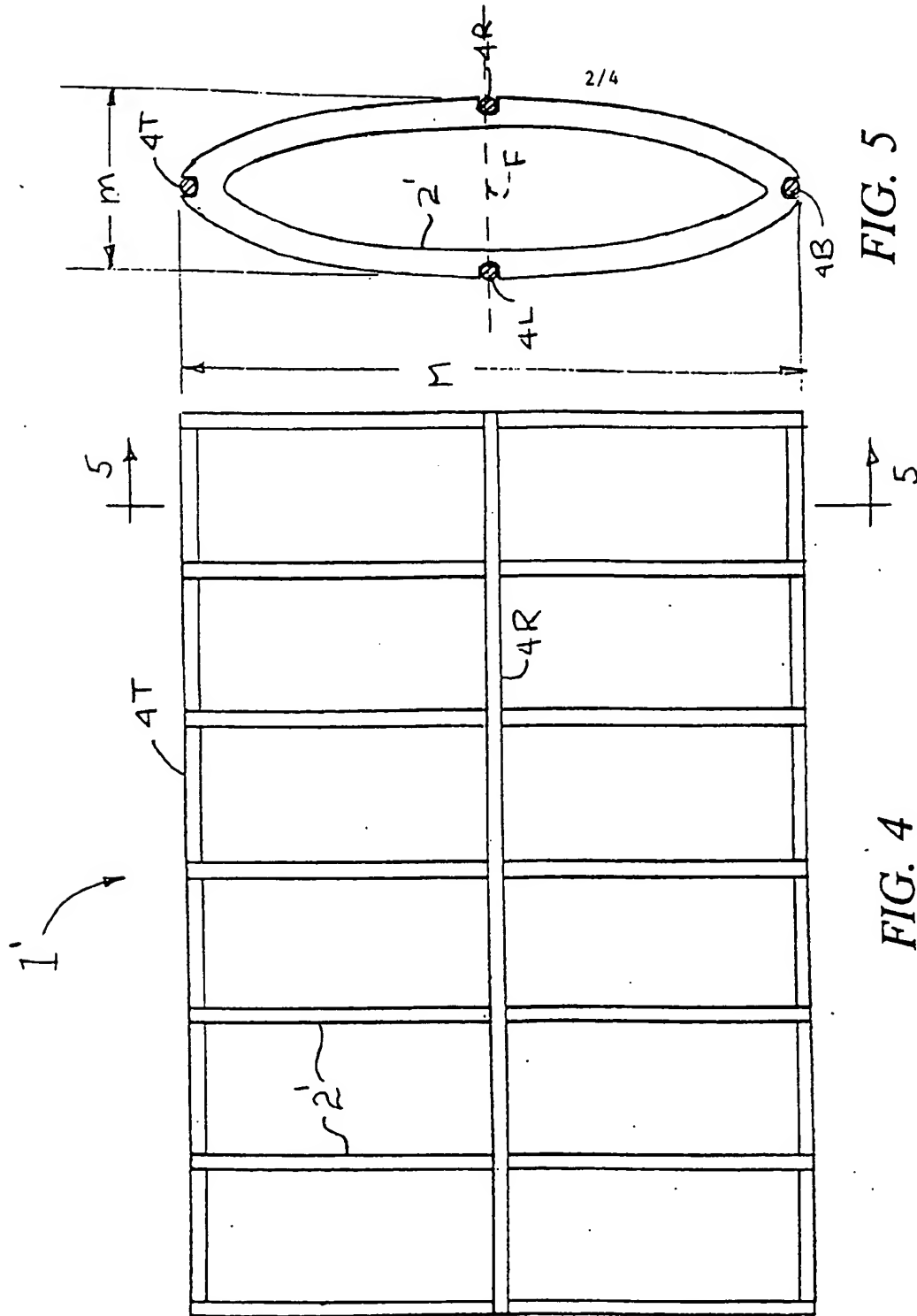


FIG. 3



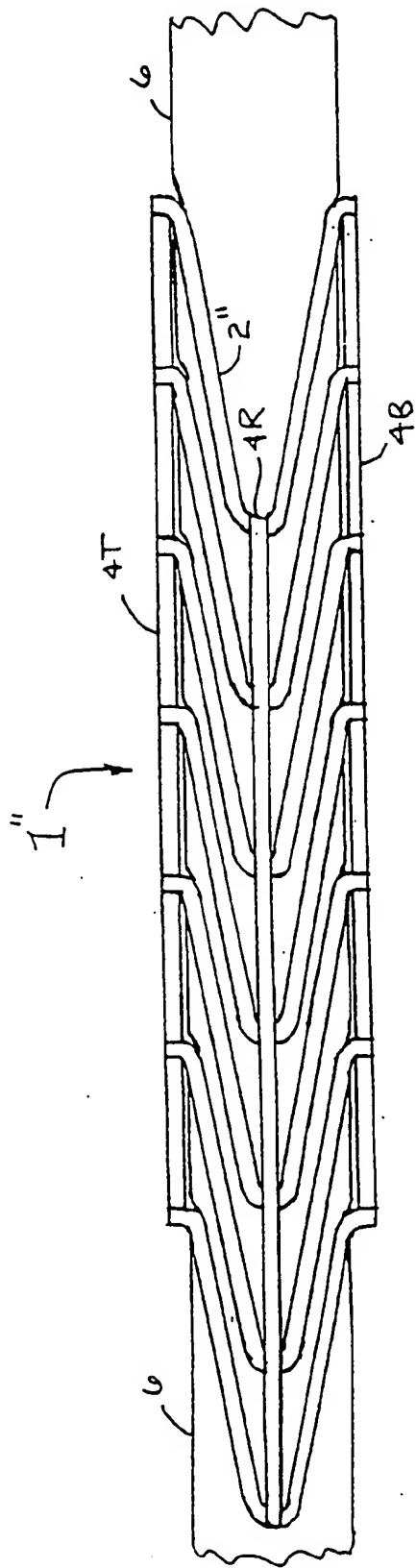


FIG. 6

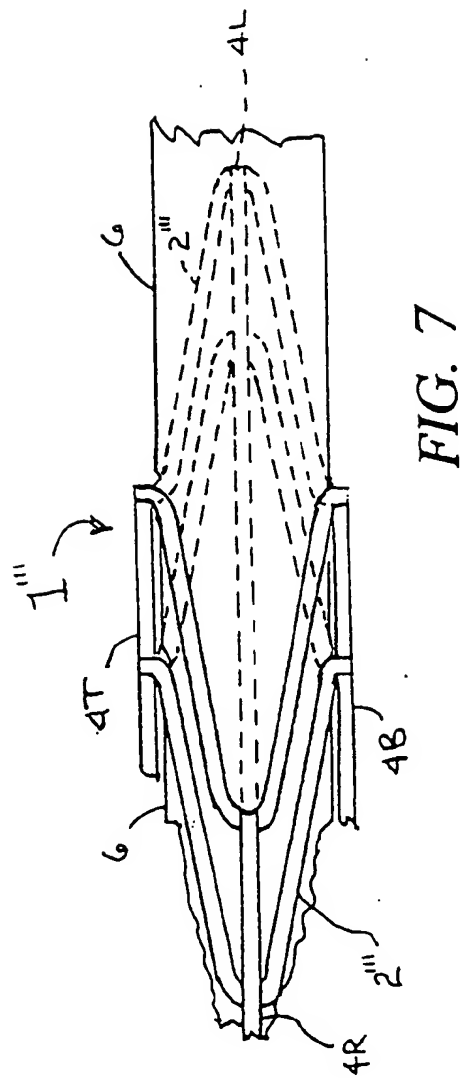


FIG. 7

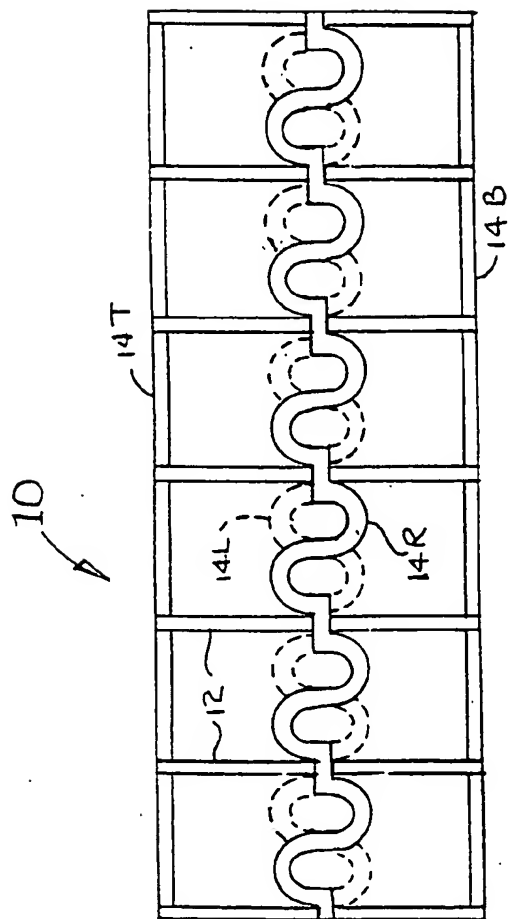


FIG. 8

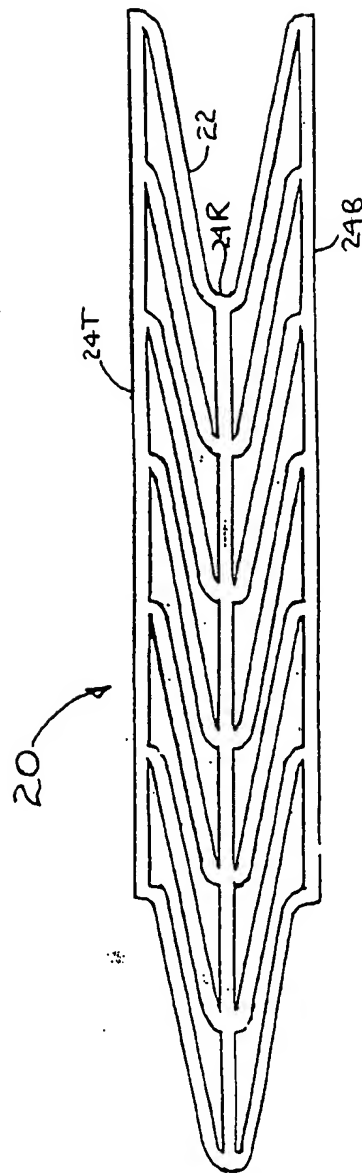


FIG. 9